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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/018,026 | 06/11/2002 | Atle Bjornerud | NIDN-10403 | 4684 |

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| EXAMINER | |
|---|---|
| SMITH, RUTH S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3737 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 11/19/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/018,026 | BJORNERUD ET AL. | |
| | Examiner | Art Unit | |
| | Ruth S. Smith | 3737 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *24-29,32 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-29,32,33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 27, 2008 has been entered.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24,32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mistretta et al in view of Stark et al ( “Magnetic Resonance Imaging”) alone or further in view of Schurfeld et al (“Renovascular hypertension-a factor of progression?”) or Lerman et al. Mistretta et al disclose a method of MRA which includes administering by injection a bolus of a blood pool MR contrast agent, generating a contrast enhanced MR image of a body part during the first pass of the contrast agent, generating at least one further MR image of the body part in a “steady state” portion of the exam when the contrast agent has become substantially uniform. Mistretta et al disclose that it is

known to image the kidney in examining the vasculature. Stark et al disclose using MRA to examine the kidney to determine the presence of abnormalities such as renal stenosis. The MR data obtained by Stark et al is indicative of renal stenosis. Schurfeld et al disclose that "a higher grade renal artery stenosis causes a reduced arterial perfusion..." Lerman et al disclose on page 1462 that perfusion correlates significantly with severity of stenosis. Therefore, the MR data obtained by Stark et al which is "indicative" of renal stenosis grade is inherently also "indicative" of renal perfusion. It would have been obvious to one skilled in the art to have modified Mistretta et al such that the method is used to examine the kidney and to determine the presence or absence of any conditions which can cause known abnormalities such as renal artery stenosis grade, renal perfusion, intra-parenchymal blood volume and parenchymal damage. The modification merely involves using the known method of examining vasculature, as disclosed by Mistretta et al, on the kidney to provide a diagnosis of such an organ as taught by Stark et al.

Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mistretta et al in view of Stark et al ( "Magnetic Resonance Imaging") alone or further in view of Schurfeld et al ("Renovascular hypertension-a factor of progression?") or Lerman et al as applied to claim 24 above, and further in view of Berg et al. Berg et al disclose MRI where a blood pool contrast agent comprising a superparamagnetic contrast agent is used. The contrast agent can include the particles as set forth in claims 26,27. It would have been obvious to one skilled in the art to have further modified Mistretta et al such that the contrast agent is the one disclosed by Berg et al. Such a modification merely involves the substitution of one known type of blood pool contrast agent for another.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mistretta et al in view of Stark et al ( "Magnetic Resonance Imaging") alone or further in view of Schurfeld et al ("Renovascular hypertension-a factor of progression?") or Lerman et al as applied to claim 24 above, and further in view of Fischer. Fischer discloses the use of a $T_2$*- weighted image during a first pass of an MR contrast agent. It would have been obvious to one skilled in the art to have further modified Mistretta et al such that

during the first pass of the contrast agent a $T_2$*- weighted image is generated. Such a modification merely involves the substitution of one known type of image generated during the first pass of a contrast agent for another.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mistretta et al in view of Stark et al ( "Magnetic Resonance Imaging") alone or further in view of Schurfeld et al ("Renovascular hypertension-a factor of progression?") or Lerman et al as applied to claim 24 above, and further in view of McMurray et al. McMurray et al disclose the use of a $T_1$- weighted image in combination with an MR contrast agent. The advantage of using a $T_1$- weighted image is well known in the art. It would have been obvious to one skilled in the art to have further modified Mistretta et al such that during the steady-state portion of the examination a $T_1$- weighted image is generated. Such a modification merely involves the substitution of one known type of image generated during a steady state portion of an MR contrast enhanced method for another.

### *Response to Arguments*

Applicant's arguments filed August 27, 2008 have been fully considered but they are not persuasive. The example, referred to by the applicant as seen on pages 16-18 of the specification, fails to show that data indicative of stenosis grade would not be indicative of renal perfusion. The claims fail to set forth that in a single examination quantified data for both renal perfusion and renal stenosis grade is provided. The claims merely set forth that the values derived from the images are **indicative** of renal perfusion and renal artery stenosis grade.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

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